

ACCURACY AND PERFORMANCE OF A NOVEL 3D METAL PRINTED ORTHODONTIC BRACKET

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A thesis submitted to the faculty at the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Master of Science in the School of Dentistry (Orthodontics).

Chapel Hill
2017

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ABSTRACT

Christina B. Jackson: Accuracy and Performance of Novel 3D Metal Printed Orthodontic Brackets
(Under the direction of Ching-Chang Ko)

3D metal printing is an emerging technology with potential to streamline bracket production for personalized and precision orthodontics. We hypothesized that the dimensional accuracy and shear bond strength (SBS) of 3D metal printed brackets are comparable to that of conventionally manufactured brackets. A novel .022 inch bracket was designed in Solidworks™, 3D printed in 316-SS via direct metal laser sintering (DMLS), and compared to two commercial bracket systems: Damon and Ti-Orthos (N=35 per system). Slots were visualized by stereomicroscope and measured with software by two examiners. SBS was measured by Instron universal testing machine. A one-way ANOVA and Tamhane's H2 statistical analyses were performed. The 3D printed slot (.0221±.001in.) was found to be more accurate than control bracket slots (Damon=.0246±.001in.; Ti-Orthos=.0245±.005in.) ($p<.001$). There was no difference in SBS of the three systems ($p=0.9$). Our data support the use of 3D metal printing for the orthodontic bracket manufacture.

ACKNOWLEDGEMENTS

Thank you to my committee members, Dr. Ko, Dr. Hershey, and Dr. Stevens, for your expertise, guidance, and advice throughout my project. Thank you to Yang-Ting Lee and John Whitley for your laboratory assistance. Thank you to Anmar Kensara and Robert Warren for your research assistance. Thank you to Dr. Feng-Chang Li for the statistical analysis of the study data. Thank you to the Southern Association of Orthodontists and the Dental Foundation of North Carolina, Inc. for the generous research grants. Thank you to my husband, Robert, for your selfless support and encouragement of my never-ending studies, all while helping to care for our young family.

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LIST OF ABBREVIATIONS

3D	Three Dimensional
CAD/CAM	Computer-Aided Design and Computer-Aided Manufacturing
DMLS	Direct Metal Laser Sintering
N	Newtons
MPa	Megapascals
SBS	Shear Bond Strength
STL	Stereolithography File

LIST OF SYMBOLS

Θ Theta, denotes an angle

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DIMENSIONAL ACCURACY OF A NOVEL 3D PRINTED ORTHODONTIC BRACKET

Introduction

Metal orthodontic brackets are primarily manufactured by two conventional methods: investment casting and metal injection molding (MIM). Following the bracket body construction, a metal mesh to retain composite for bonding to enamel is welded onto the base¹. The expense and time required for fabrication of casts and molds are prohibitive for low volume productions, such as that of custom brackets. A more time and cost effective manufacturing method for orthodontic brackets would be beneficial.

3D metal printing is an emerging technology with the potential to streamline bracket production for personalized and precision orthodontics. 3D printing is an additive process of manufacturing in which layers of material are added by computer control to produce a finished product. 3D printing is commonly performed with polymers; however, metal 3D printing has been in use since the mid-1990s.² 3D printing with metal can be accomplished by melting or sintering metal powder via laser or electron beams as instructed by computer-automated design/computer-aided manufacturing (CAD/CAM)³. Metal printing can be performed with both stainless steel and titanium alloys, materials commonly used in orthodontic brackets because of their biocompatibility and resistance to intra-oral corrosion. With metal powder layer thicknesses ranging from 15-500uM, this method of manufacturing is ideal for small, precise parts⁴.

One limitation of conventional manufacturing is the exclusion of features with undercuts that would prevent removal of the part from the mold. 3D metal printing permits retentive features with undercuts to be printed directly into the base of a bracket, making it unnecessary to stamp a foil mesh to the base for retention of composite. This allows the bracket to be manufactured in one piece and streamlines the production process.

Another limitation of conventional manufacturing methods is the dimensional accuracy of the archwire slots. When the archwire slot is larger than prescribed, the excess space between the archwire and bracket (“play”) allows the archwire to roll within the slot, reducing the amount of torque expressed by the bracket. The height of the bracket slot relative to the archwire height reduces the torque by the amount Θ , as defined by equation (1):

$$\text{Equation (1)} \quad H = w \cdot \sin \Theta + h \cdot \cos \Theta$$

where H is the height of the bracket slot, w is the width of the archwire, and h is the height of the archwire, as shown in Figure 1.

Standards for orthodontic brackets were introduced in 1993 to regulate the nominal dimensions of orthodontic brackets and their tolerance limits, and are summarized in DIN 13971-2.⁵ For a .018 inch slot, the lower limit of the slot size corresponds to the nominal slot size (.018 inches, i.e. 0.46mm). The upper limit is .0197 inches, i.e. 0.5mm. For a .022 inch slot, the lower limit of the slot size corresponds to the nominal slot size (.022 inches, i.e. 0.558 mm). The upper limit is .024 inches, i.e. 0.599mm, the maximum size allowed by DIN 13971-2.

Much research has been performed on the accuracy of commercially available bracket slots, with equivocal results. Cash et al. measured the slots of 11 bracket systems, and found that

all were oversized, some by as much as 17%.⁶ Kusy et al. measured the slots of 24 bracket systems, and found that about 15% of bracket slots were smaller than nominally stated, which is below the limit defined by DIN 13971-2.⁷ Additionally, some of the slots exceeded the nominal value by as much as 16%. Joch et al. measured the slot sizes of five different 0.022 inch bracket systems and found that all bracket slot heights were within the upper and lower tolerance limits defined by DIN 13971-2.⁸ Bhalla et al. measured five self-ligating bracket systems and found that all were statistically significantly larger than the stated sized, some by as much as 14%.¹⁰ The reason for the variety of results may be because of variations in fabrication techniques, discrepancies produced between batches by the manufacturer, or inconsistencies in measuring technique.

In order to validate the use of 3D metal printing for the fabrication of orthodontic brackets, we hypothesize that the size of the archwire slots meets the standards outlined in DIN 13971-2. If the precision of this manufacturing method can produce more accurate archwire slots, it could lead to improved patient outcomes and shorter treatment times.

The aim of this study was to assess the dimensional accuracy of novel one-piece 3D metal printed orthodontic brackets. Additional factors affecting the quality of 3D metal printed orthodontic brackets were examined.

Materials and Methods

A novel one-piece 0.022 inch central incisor bracket with retentive features in the base was designed in Solidworks® (Dassault Systems, Vélizy-Villacoublay, France) and 3D printed in 316-stainless steel by Proto Labs® (Maple Plain, MN, USA) on an Mlab cusing machine (Concept Laser, Lichtenfels Germany) via direct metal laser sintering (DMLS) with a layer

thickness of 20 microns (0.0008 in.). The resulting brackets were evaluated along with those from two conventionally manufactured commercially available bracket systems, Damon and Ti-Orthos (Ormco, Orange, CA, USA) (N=35 per system). The slots of each bracket were visualized by stereomicroscope (Nikon SMZ18, Melville, NY, USA) and the slot width was measured with software (Nikon NIS Elements Basic Research) by two examiners.

Sixteen brackets were polished in a post-processing step by G&H Orthodontics (Franklin, IN, USA) in a centrifugal disc finishing machine with crushed walnut shells. The centrifugal disc finishing unit was set at 300 rpm for 30 minutes, the parts were inspected, and a second cycle was performed for one hour. The slots of the polished brackets were measured in the same manner.

Intra-class correlation coefficients for the slot size measurements by the two examiners were 0.77, 0.71, and 0.88 for the DMLS, Ti-Orthos, and Damon brackets, respectively. There were two main sources of error in measuring the slots. The first is that the slot edges are beveled, which makes it difficult at times to distinguish the edge of the slot, a complication that has been noted in previous studies.¹¹ The second is that the slot is angled relative to the bracket base, and so care must be taken to measure only the edge and not the wall of the slot. These errors were overcome by adjusting the light until a clear edge of the slot could be visualized, and by measuring the sides of the slots, rather than the top of the slots, to better isolate the edges.

Statistical analysis

Means and standard deviations were calculated and repeatability was assessed using an intra-class correlation coefficient. The distribution of the data was found to be normally distributed by the Kolmogorov-Smirnov procedure. To test the null hypothesis of no difference

between the groups, a one-way ANOVA was performed with a Tamhane's T2 test because of unequal variance, demonstrated by the Levene's test. A paired t-test was performed on the right vs. left slot sizes of the 3D printed bracket. An unpaired t-test was performed on the unpolished and polished brackets. The significance level was set to $P=0.05$.

Results

The mean slot size, range, and standard deviation of the bracket slots are presented in Table 1. The results of this study reject the null hypothesis that there is no difference in the accuracy of the 3D printed slot and the control brackets. The 3D printed slot ($.0221 \pm .001$ in.) was found to be closer to the prescribed .022 inches than control bracket slots (Damon= $.0246 \pm .001$ in.; Ti-Orthos= $.0245 \pm .005$ in.) ($p < .001$). The mean slot size of the 3D printed bracket was the only one measured that was within the range set by DIN 13971-2. The two control brackets measured both had mean slot sizes above the upper limit of 599 microns.

The variation in the Ti-Orthos brackets was the lowest ($SD=14.7$ microns), followed by Damon ($SD=23.6$ microns). The 3D printed bracket had the largest variation in slot size ($SD = 30.4$ microns) ($p < .001$). Variation was also observed in the right vs. left sided slots of the 3D printed bracket. The right sided slots were smaller (0.0182 ± 0.002 in.) than the left sided slots (0.0206 ± 0.001 in.) ($p < .001$). There was no difference in the size of the polished vs. unpolished brackets ($p=0.87$).

Discussion

This study presents, for the first time, data to support the use of 3D printing for the manufacture of orthodontic brackets. There are many possible advantages of using 3D

printing for manufacturing orthodontic brackets, one of which is shown in this study to be that the archwire slot will be closer to the prescribed size than conventionally manufactured brackets. Theoretically, this will reduce the third order “play” in the bracket and result in a more optimal final tooth position without requiring additional bends, which will result in greater efficiency and shorter treatment times. The mean sized 3D printed slot will have just 0.3 degrees of play, while the largest 3D printed slot measured will have 7.1 degrees of play.

The mean slot sizes of both the Damon and Ti-Orthos brackets were larger than the upper limit of DIN 13971-2. One of the main reasons that archwire slots are oversized, outside of naturally occurring manufacturing tolerances, is to ensure that there is always enough clearance to accommodate insertion of the archwire. However, it has also been shown that archwires tend to be smaller than the stated size, for the same reason.^{7,8} As such, it is not necessary to have archwire slots larger than stated by .01” or more, as is seen in some commercial bracket slots.¹² Using Eq. 1, an archwire of stated size placed in a mean-sized Ti-Orthos or Damon slot will have 6.8 degrees of play. An archwire placed in the maximum sized Ti-Orthos or Damon slots measured will have 10.3 and 13.5 degrees of play, respectively.

While the mean 3D printed slot size is closest to the prescribed .022 inches, or 0.558mm, it also had the largest variation in size, as indicated by the range and standard deviation. The Damon and Ti-Orthos brackets had statistically significantly smaller standard deviations. One reason for the high variance in the 3D printed bracket was because of the surface finish of the bracket slot edge. Some brackets had small bumps or extrusions on the slot surface. The edge of the slot was measured as the narrowest part, and so the presence of any extrusions made the effective slot size smaller. Another reason for the high standard deviation is that a statistically significant difference was found between the size of the right and left slots, due to the orientation

of the bracket during printing. Manufacturing engineers design a scaffold that prints along with the product to support overhanging structures, which in the brackets are the tie wings. As such, the bracket was printed at an angle to the horizontal with supports below the tie wings, with the right side closer to the printing plate. The right sided slots were measured to be smaller than the left sided slots by an average of 23 microns ($p < .001$).

The smallest 3D printed slot size measured was 463 microns, or .0182 inches, due to the presence of extrusions on the slot surface. This slot is smaller than the lower limit set by DIN 13971-2 and will not allow the insertion of a perfectly sized .021x.025 archwire, although it may accommodate an undersized archwire of that stated size. There would be no difficulty inserting a .018x.025 or .019x.025 wire, commonly used in finishing stages. None of the Damon or Ti-Orthos brackets measured were below the nominal stated size of .022 inches. So while there will be less play in a 3D printed slot, some of the undersized slots may make it difficult to insert a fully sized .021x.025 archwire.

The surface finish is affected by the orientation of the bracket during printing; the surface facing the printing plate will have a rougher surface. While one may expect that the average slot size would increase after polishing due to the removal of extrusions on the slot surface, it was found that with this polishing method, there was no difference in the slot sizes before and after polishing. Future studies will explore the surface finish quality of brackets printed at different orientations to the printing plate and polished by alternate methods.

3D printing has the potential to revolutionize custom bracket manufacturing, as it is much more cost and time effective than methods requiring a mold, particularly for small quantities. The total time to print the experimental bracket was approximately 90 minutes, at a cost of seven dollars per bracket, which will vary by quantity and manufacturer. New design features can be

incorporated into the bracket, for example the retentive undercuts that are manufactured directly into the base of the experimental bracket. For patients with unique tooth anatomy, it can be advantageous to produce a custom bracket for more accurate bonding and tooth control. And as it has been shown here that 3D printing can produce brackets with more accurate archwire slots, effective torque and ultimate tooth position may be improved and treatment time may be reduced.

Conclusions

1. The 3D printed slot had the smallest mean slot size compared to the Damon and Ti-Orthos brackets, and was within the limits prescribed by DIN 13971-2. ($p < .001$)
2. The 3D printed slot had the largest variation in measured slot size. ($p < .001$)

Table 1. Vertical slot dimensions of bracket systems

Slot size in mm					
Bracket Type	N	Min.	Max.	Mean	SD
DMLS	35	0.463	0.631	0.561	0.030
Damon	35	0.583	0.692	0.625	0.024
Ti-Orthos	35	0.596	0.664	0.623	0.015
Slot size in inches					
DMLS	35	0.0182	0.0248	0.0221	0.0012
Damon	35	0.0230	0.0273	0.0246	0.0009
Ti-Orthos	35	0.0235	0.0261	0.0245	0.0006

p<.001

Table 2. Right vs. left slot sizes of the 3D printed bracket

DMLS slot size in mm					
	N	Min.	Max.	Mean	SD
Right side	35	0.463	0.607	0.548	0.047
Left side	35	0.522	0.631	0.571	0.030
Slot size in inches					
Right side	35	0.0182	0.0239	0.0216	0.0019
Left side	35	0.0206	0.0248	0.0225	0.0012

p<.001

Table 3. Unpolished vs. polished slot sizes of the 3D printed bracket

	N	Mean (mm)	Mean (in)	SD
Unpolished	16	0.561	0.0221	0.014
Polished	16	0.553	0.0218	0.001

p=.887

Figure 1. Reduction in effective torque of an archwire in a larger slot

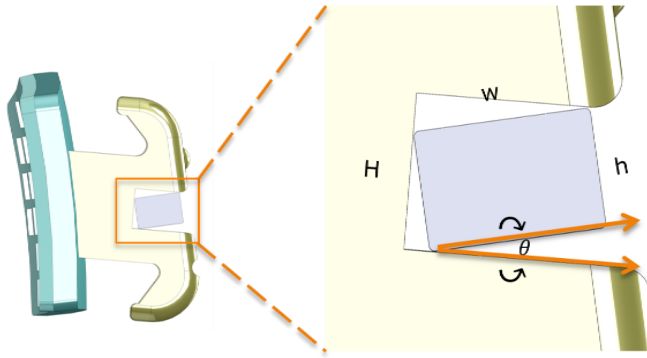


Figure 2. Mean + 1 SD of slot size for each bracket system with upper and lower limits given by DIN 13971-2

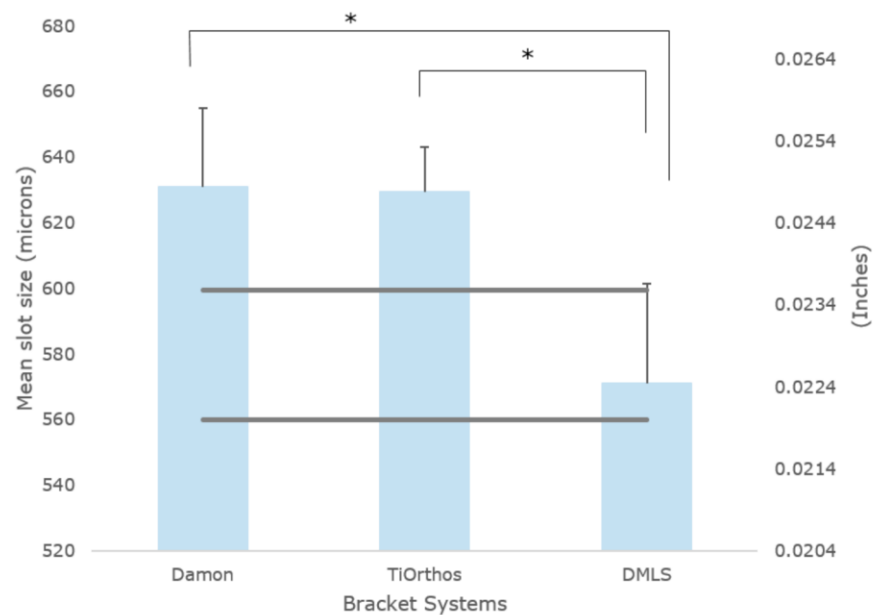
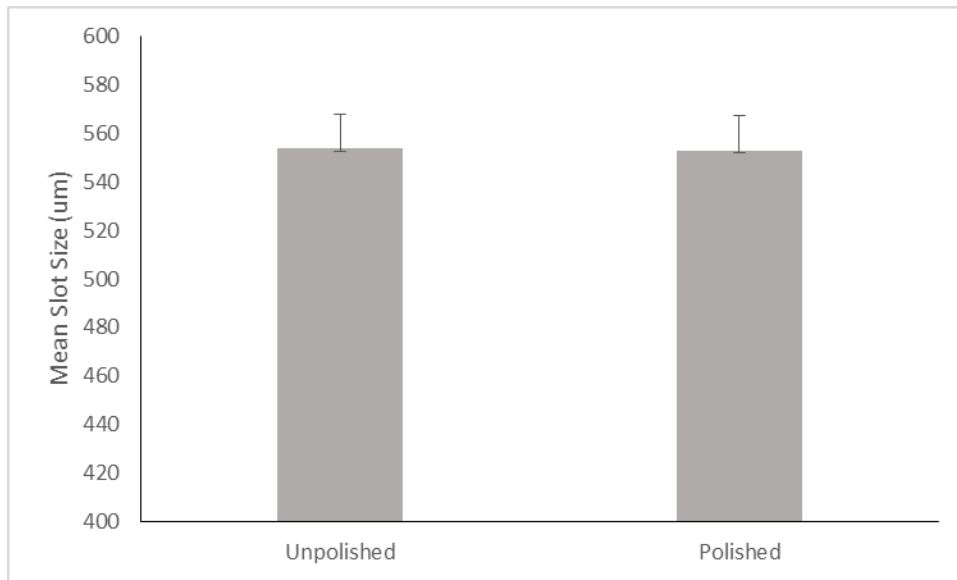


Figure 3. Mean+1 SD of slot size of 3D printed bracket before and after polishing



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SHEAR BOND STRENGTH OF A NOVEL 3D PRINTED ORTHODONTIC BRACKET

Introduction

Orthodontic brackets are bonded to enamel with adhesives that are retained to the bracket via perforations in the base. Although most metallic brackets use a soldered foil mesh for composite retention^{1,2}, some rely on retentive features such as grooves or concavities that are milled into the base, referred to as integral brackets.^{3,4} Metal orthodontic brackets are currently manufactured by two conventional methods: investment casting and metal injection molding (MIM). For each of these methods, a metal mesh for retention of composite is welded onto the base in a post-processing step⁵; these are referred to multi-piece brackets in the following text. Studies have found multi-piece brackets to have comparable bond strength to integral brackets^{6,7}. Bond strength relies on many factors, not limited to the architecture and surface area of the bracket base, composite strength, tooth preparation, and bonding protocols.⁸⁻¹¹

Initially developed for applications in architecture and manufacturing, 3D metal printing, an emerging technology, can potentially streamline bracket production for personalized and precision orthodontics. 3D printing allows for a bracket to be customized with curved freeform surfaces to fit individual teeth, and for undercuts to be fabricated, with which retentive features can be manufactured directly into the base. The direct printing of such features eliminates the need to solder a mesh foil to the back of the bracket.

In the present study, two one-piece brackets were designed with retentive features in the base and fabricated via 3D metal printing. A study was previously performed in which the

dimensional accuracy of the 3D printed bracket slots were found to be more accurate than conventionally manufactured bracket slots. This study now explores the shear bond strength of the retentive features printed into the base of the bracket. We hypothesize that there will be no difference in the shear bond strength of the 3D metal printed bracket compared to the existing products with a foil mesh soldered to the bracket base.

Materials and Methods

3D Printed Bracket

Two novel one-piece .022 inch central incisor brackets were designed in Solidworks® (Dassault Systems, Vélizy-Villacoublay, France) with square undercuts in the base; one with undercuts measuring 0.39x0.39x0.13 mm and another with undercuts measuring 0.39x0.39x0.33 mm, each with an inward draft of 5 degrees. The brackets were 3D printed in 316-stainless steel by Proto Labs (Maple Plain, MN, USA) on an Mlab Cusing metal printer (Concept Laser, Lichtenfels Germany) via direct metal laser sintering (DMLS). The resulting brackets were evaluated along with those from two conventionally manufactured commercially available bracket systems, Damon and Ti-Orthos (Ormco, Orange, CA, USA) (N=13-20 per system).

Shear Bond Test

A cylindrical mounting jig was constructed of chemical-cure acrylic resin. An 8mm recess with non-uniform undercuts was created in the center of the jig with an acrylic bur; a thin layer of bonding agent (Ortho Solo™, Ormco, Orange, CA) was applied to the surfaces of the recess, and composite (Transbond™ XT, 3M Unitek, Monrovia, CA) was incrementally cured until it extended just beyond the surface of the acrylic. A thin layer of bonding agent was applied to the surface of the cured composite and thinned with a two-second gentle stream of air.

Composite was applied to the base of the test bracket. The brackets were mounted to the center of the jig, with excess composite removed at the edges with an explorer so that none overlapped with the edge of the base. The composite was cured as per the manufacturer's instructions for 6s on the mesial and distal surfaces of the bracket. Brackets were cured with an Ortholux™ Luminous Curing Light (3M Unitek, Monrovia, CA). The light intensity was 1600mW/cm² according to the manufacturer, which was verified using a dental radiometer (Bluephase® Meter, Ivoclar Vivadent.) Specimens were placed in a sealed bag with distilled water at room temperature for 24 hours, at which time they were tested.¹¹

An Instron® Universal Testing Machine (E3000, Instron®, Canton, MA) was configured for shear bond strength testing. A 5 kN load cell was calibrated. The acrylic jig was secured in a cylindrical clamp such that the bracket slot was parallel to the horizontal by visual inspection. A sharpened chisel blade was positioned just above the bracket base at the bracket-composite interface to isolate the shear mode of failure.¹² The blade was lowered at a crosshead speed of 0.5mm/min until the bracket debonded. If the blade slipped off of the bracket base during loading, the sample was discarded. The force providing failure was recorded in Newtons, denoted as shear bond strength, and converted into shear bond strength per area in megapascals by dividing the measured force values by the mean surface area of the brackets as measured by stereomicroscope software (Nikon SMZ18, Melville, NY, USA; Nikon NIS Elements Basic Research software).

Statistical analysis

Means and standard deviations were calculated. The distribution of the data was found to be non-parametric by the Kolmogorov-Smirnov procedure. To test the null hypothesis of no

difference between the groups, a Welch test was performed with a Tamhane's T2 test because of unequal variance, demonstrated by the Levene's test. The significance level was set to $p=0.05$.

Results

The overall mean bond strengths were 202.89 ± 30.02 , 245.45 ± 27.40 , 237.31 ± 77.92 , and 234.12 ± 62.19 N for the two 3D printed bracket designs, the Damon, and Ti-Orthos brackets, respectively (Table 4). It was determined that there was a difference in the shear bond strength between the two 3D printed bracket designs ($p=.003$), but that there was no statistically significant difference in the shear bond strength of the two 3D printed bracket designs compared to the control brackets.

The SBS per area increased the difference in strength between the experimental and control brackets because the control brackets had slightly smaller bases, thus the strength was higher. The overall mean bond strength per area were 14.85 ± 2.20 , 17.96 ± 2.01 , 23.19 ± 7.61 , and 19.22 ± 5.11 MPa for the two 3D printed bracket designs, the Damon, and Ti-Orthos brackets, respectively (Table 5).

It was determined that there was a statistically significant difference in the SBS per area of the first 3D metal printed bracket base design and the Damon and Ti-Orthos controls, but that there was no difference in the SBS per area of the second bracket design and the controls. The SBS per area of all the brackets tested were well above an often cited guideline for clinically acceptable bond pressure of 8 MPa.¹³

Discussion

The results of this study show that there is no statistically significant difference between the novel one-piece 3D metal printed brackets with retentive features printed directly into the base and the conventionally manufactured brackets with a mesh pad welded to the bracket base. Thus, we accept the null hypothesis that there is no difference in the bond strength between the experimental 3D metal printed bracket and the controls. When adjusted for the size of the bracket base, one of the experimental bracket designs failed at a lower bond strength, while the other performed as well as the controls.

Many factors influence the bond strength of brackets. Considering only the design of the bracket base, some conclusions have been drawn from previous studies about what makes a bracket more retentive. It has been found that for bracket with a mesh, a finer mesh with a rough surface has the highest bond strength.⁶ Sand blasting bracket bases improves the bonding by increasing the surface area/roughness.¹⁴⁻¹⁶ It is recommended that the mesh be 60 gauge, as smaller gauge wires allow more area for the composite to penetrate, enabling a better bond.^{6,10,11,17} There is no difference in shear bond strength between a single and double layer mesh.¹⁸ Some studies have shown that integral, machined bases have poorer retention, due in part to air trapping or reduced surface area for bonding, but others studies show no reduction in bond strength.^{4,7,14,19} Bond strengths were shown to improve when using a highly filled resin cement, such as Transbond XT, the composite used in this study.⁴

Features of the experimental bracket base designed to enhance retention include: an increased number of recesses for composite retention compared to integral base designs formerly on the market (i.e. Edgeway (Ortho Organizers, Carlsbad, CA) and Dynalock (Unitek, Monrovia, CA), a five degree tapered undercut from the surface of the base, and recesses that are small for

increased surface area, yet large enough for the flow of composite. Two unique features of this design, the undercuts and the small recesses, are permitted due to their 3D metal printing fabrication. These features would otherwise be impossible to fabricate by casting or milling.

According to a study by Reynolds, the minimum acceptable shear bond strength required for orthodontic brackets ranges from 5.8-7.8 MPa.¹³ Suggestions for the clinically acceptable bond strength do not take into account the debond force location on the bracket; however, it has also been shown that tensile vs. shear/peel tests produced no significant difference in bond strength.²⁰ The upper limit of bite force on a central incisor is 175-245N²¹, thus the experimental central incisor bracket design is appropriate for clinical use.

The experimental bracket design with shallower undercuts had a lower bond strength (N) than the experimental design with deeper undercuts, as expected, and had a lower bond pressure (MPa) than the control brackets. However, all brackets had bond pressures were above the clinically acceptable limit. A bracket with lower bond strength that will still withstand normal chewing forces can be advantageous because it may reduce the risk of enamel fractures or damage during debond by promoting failures at the bracket/adhesive interface.²²⁻²⁴

This study confirms that a one-piece 3D metal printed bracket with retentive features printed directly in the base will perform as well to resist shear bonding as the control bracket systems with mesh grids. The findings of this study further promote the use of 3D metal printing for custom orthodontic bracket manufacturing.

Conclusions

- 1) Both of the one-piece bracket base designs did not statistically significantly differ from the control brackets in shear bond strength (N)
- 2) One of the 3D printed bracket base designs did not statistically significantly differ from the control brackets in shear bond strength per area (MPA)

Table 4. Shear bond strength (N) of four bracket bases

Shear bond strength (N)					
Bracket Type	N	Min.	Max.	Mean	SD
3D Printed ¹	15	156.29	234.61	202.89	30.02
3D Printed ²	13	179.12	275.36	245.45	27.40
Damon	20	81.60	362.51	237.31	77.92
Ti-Orthos	18	124.57	318.87	234.12	62.19

¹ .13mm perforations in bracket base

² .33mm perforations in bracket base

Table 5. Shear bond strength per area (MPa) of four bracket bases

Shear bond strength per base area (MPa)						
Bracket Type	N	Area of base (mm ²)	Min.	Max.	Mean	SD
3D Printed ¹	15	1.37E-05	11.44	17.17	14.85	2.20
3D Printed ²	13	1.37E-05	13.11	20.15	17.96	2.01
Damon	20	1.02E-05	7.97	35.42	23.19	7.61
Ti-Orthos	18	1.22E-05	10.23	26.18	19.22	5.10

¹ .13mm perforations in bracket base

² .33mm perforations in bracket base

Figure 4. Median + IQR of shear bond strength (N) for each bracket system

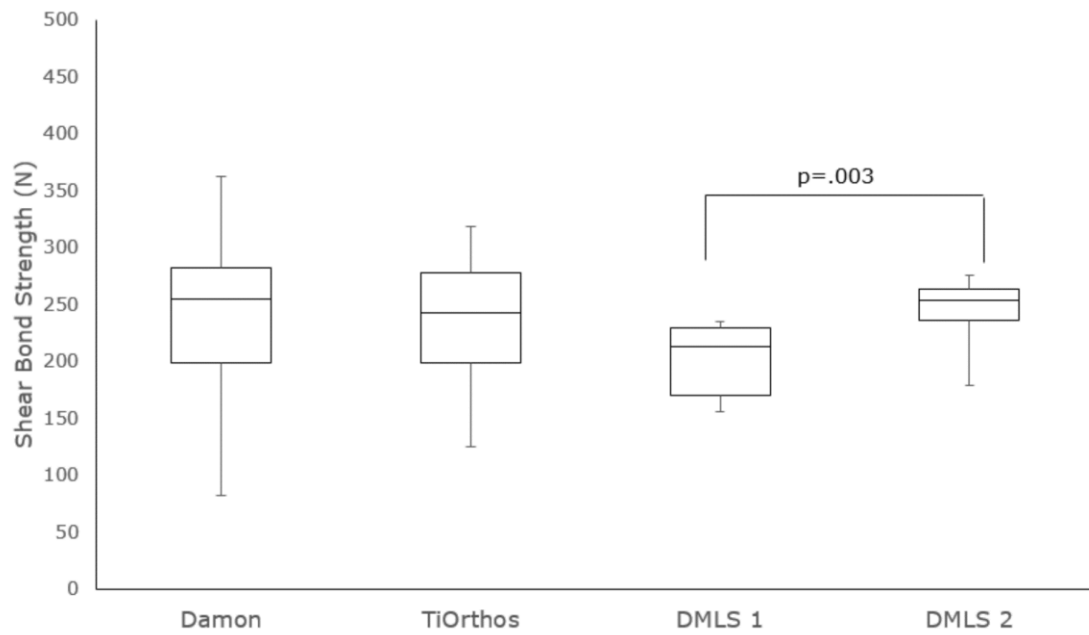
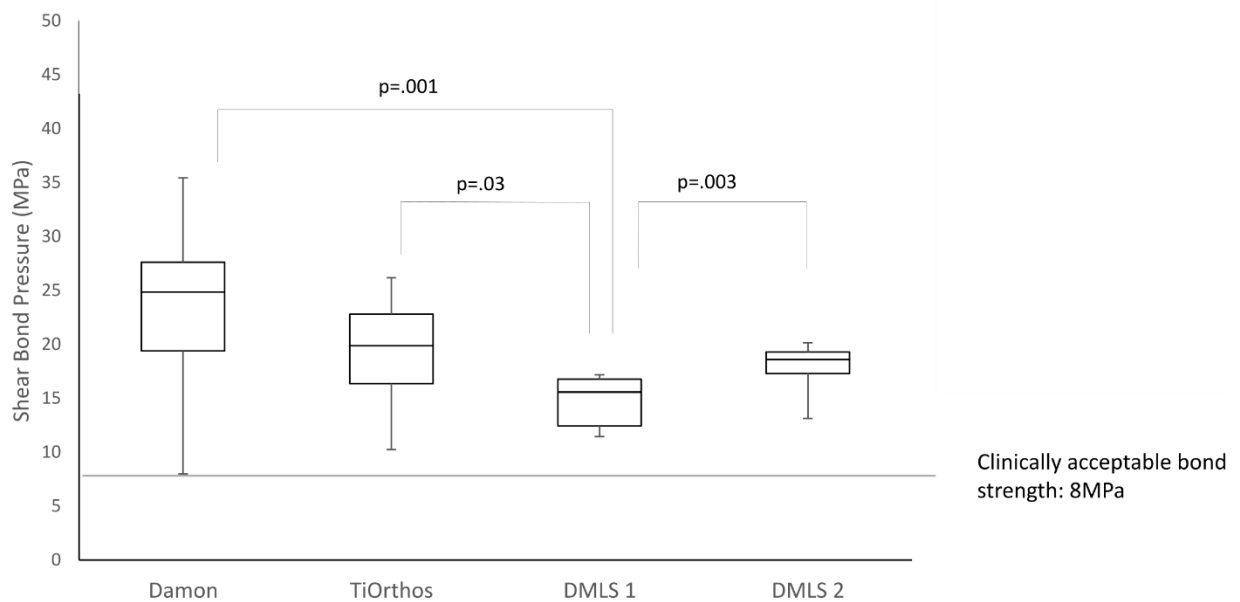


Figure 5. Median + IQR of shear bond strength per area (MPa) for each bracket system



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